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Ortho Molecular Products Inc 3017 Business Park Drive P.O Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecular products.com Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAY 25 2.2

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Gastrointestinal Support

Dietary Ingredients: Cape Aloe, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Super Aloe 450

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Mason Slason

Ortho Molecular Products

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Attachment of Super Aloe 450 Labels

Suggested Use: As a dietary supplement, 1 capsule at bedtime (allow 24 hours before redosing) or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg; dairy, pearuts, soy, yeast, artificial colors and flavors.

Notice: For occasional use only. This product contains Cape Aloe (Aloe Ferox). Do not use this if you develop diarrhea or abdominal pain. Consult your health professional if you have frequent diarrhea. (Do Not use if PRECHANT.) Nursing mothers should contact their health professionals.

As with all dietary supplements, some individuals may not tolerate or may be altergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Coase taking this product and consult your physician if you have negative reactions upon ingestion. Keep containes member accessors at ROOM TEMPERATURE. Keep out of FIEACH OF CHILDREN. This product was sealed for your protection. Do not use if outer logged nack seal or inner-seal are missing or descreted.



8 Label ID L-OMP100-820100-B

Dietary Supplement Product #820



Super Aloe 450



Supplement Facts

Serving Size: 1 Capsule Servings Per Container: 100

1 capsule contains Serving Value
Cape Alice 450 mg *

* % Daily Value not established

Other Ingredients: Natural vegetable capsules This product may contain one or more of the following. Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Divokte.

'iThese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose; trust, cure, or prevent any disease.

Mfg. by Onthe Molecular Products, inc 3017 Business Park Drive-Slevens Point, Wil. 54481

OrthoMolecularProducts.com